REMARKS

The Official Action of May 15, 2008, and the newly cited and applied prior art have been carefully studied. The claims in the application remain as claim 1-7, 9, 10, 12-20, 22, 23 and 25-30, and these claims are respectfully submitted to define both novel and unobvious subject matter. Favorable reconsideration and allowance are again respectfully requested.

Claims 9, 22 and 23 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

Claims 9 and 22 have been amended to remove GMS from the listing of hydrophilic polymers, as GMS (glycerol monostearate) is not a hydrophilic polymer, but is generally equivalent thereto, noting *Abbott v. Andrx*, 81 USPQ2d 1289, 1299-1301.[1]

Claim 23 has now been amended to make it dependent on and from claim 7, thereby overcoming the rejection of claim 23.

Withdrawal of the rejection is in order and is respectfully requested.

[1] As is well known, GMS is the abbreviation commonly used to denote glycerol monostearate. Claims 1 and 29 are amended above to separate GMS from the hydrophilic polymers.

Claims 1, 3, 4, 16, and 19 have been rejected under Section 102 as anticipated by newly cited and applied Heiligenstein EP0 919 236 (Hiligenstein or the "publication"). This rejection is respectfully traversed.

First, duloxetine (sold in the United States by Eli Lilly under the name Cymbalta), the focus of Hiligenstein, is a compound entirely different, both chemically (structurally) and physically from venlafaxine, the compound which comprises the active ingredient of the claimed extended release composition.[2] Yes, applicant recognizes that venlafaxine is also mentioned (page 3, lines 8-10) among other compounds including duloxetine, but it is only for duloxetine that Hiligenstein shows an example and provides an enabling disclosure.

The cited publication is primarily directed to the use of norepinephrine uptake inhibitors in the treatment of oppositional defiant disorder. On page 3, line 18 to page 4, line 8, the publication discloses a specific enteric formulation of the active compound duloxetine. It would appear from the wording of the Office Action that the Examiner considers that a formulation similar to the duloxetine

[2] The water soluability of duloxetine is reported to be 0.00296 mg/mL.

formulation given in the specific example may also be applied to venlafaxine hydrochloride, whereby the Examiner concludes that Hiligenstein anticipates the rejected claims in spite of (1) the different drug and (2) the different coating.

In response, Applicant notes that the example disclosed in the above passage of the cited publication specifically relates to a preferred enteric formulation of duloxetine. Moreover, the term "duloxetine" is defined in the publication to refer to acid addition salts or to the free base of the molecule duloxetine (page 3, lines 6-7). Consequently, for the above mentioned reasons, the particular formulation disclosed in the cited art clearly does not comprise venlafaxine hydrochloride.

This point is further emphasized by the fact that the cited publication does not provide any general disclosure of an enteric formulation that would be appropriate for a range of active compounds, including venlafaxine. Rather, the duloxetine enteric formulation is given as a specific example of a formulation that may be used in order to work the claimed invention, namely for the specific use of norepinephrine uptake inhibitors in the treatment of a specific class of disease.

Furthermore, it is to be recognized that although venlafaxine shares some important medicinal properties with

duloxetine, the two compounds are, chemically, entirely unrelated. There is thus no *a priori* reason to believe that a formulation that is disclosed for use with duloxetine would be suitable for use with venlafaxine, a compound that has a completely different chemical structure. Consequently, Applicant believes and respectfully submits that the duloxetine example given in the prior art publication does not, and indeed could not, provide an implicit or generic disclosure that includes the instant venlafaxine formulation including a controlled release coating within its scope.

Applicant therefore believes that a person skilled in the art cannot directly and unambiguously derive from the cited publication a formulation identical to the one specifically claimed in the present application which is instead applied to the active compound venlafaxine hydrochloride. Hiligenstein does not put the skilled worker in possession of the claimed subject matter, and does not enable such a skilled worker to come up with what is claimed.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-7, 9, 10, 12-20, 22, 23 and 25-30 have been rejected as obvious under section 103 from Hiligenstein. The rejection is respectfully traversed.

The teachings of Hiligenstein are contrary to the objectives of the present invention and therefore Hiligenstein leads the person of ordinary skill in the art in a direction away from the present invention. In this regard, Hiligenstein teaches and thus leads the skilled artisen to make an enteric formulation, whereas the objective of the present invention is to provide a controlled or extended release formulation. Thus, Hiligenstein does not and cannot teach the person of ordinary skill in the art what modifications are to be made in the Hiligenstein enteric formulation to provide an extended release formulation, because there is **no reason given for doing so**.

As stated above, the cited publication, Heiligenstein, discloses an enteric formulation of the active agent duloxetine. Thus, instant claim 1 differs from the disclosure of the cited publication with regard to at least the following two aspects:

i) Venlafaxine hydrochloride - rather than duloxetine - is used as the active compound; and
ii) The claimed composition is an extended release formulation comprising an additional polymeric layer controllably releasing venlafaxine hydrochloride.

In this regard, the objective technical problem underlying the present invention can be seen in providing a composition which, firstly, comprises venlafaxine

hydrochloride, and secondly, allows for extended release of this active compound. In contrast, the cited publication teaches an enteric formulation which provides for protection of an active compound during its passage through the stomach, in order that said active compound may be rapidly released from said formulation after the passage through the stomach has been completed.

It is respectfully contended that the hydrophobic polymer used in the prior art example, HPMCAS, is not a functional equivalent of the hydrophobic polymers described and listed in the present invention. This is for the reason that while HPMCAS, an enteric polymer, functions by preventing the disintegration of the formulation and the release of the active ingredient therefrom at the pH of the stomach, the hydrophobic polymers used in the outer layer of the present invention cause the controlled release of the active agent by other means (for example, by providing a diffusion barrier).

It may therefore be seen that the cited publication actually teaches away from the subject matter of claim 1, and leads the skilled artisan in the wrong direction, toward the use of an enteric coating rather than an extended release coating. Consequently, the present invention, as defined in the instant claims, is not rendered obvious by the teachings of the applied cited art.

Applicant respectfully notes that the present arts are very unpredictable, and even in view of *KSR*, 82 USPQ2d 1385 (Supreme Court 2007), very small changes in the present art can constitute non-obvious subject matter. In this regard, please see *In re Omeprazole Patent litigation*, 87 USPQ2d 1865, 1878-1879 (Fed Cir 2008).

Withdrawal of the rejection is in order and is respectfully requested.

Favorable reconsideration and allowance are earnestly solicited.

Respectfully submitted,

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